K013665
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JAN 2 9 2002

Medtronic Sofamor Danek
PYRAMID™ ANTERIOR PLATE Fixation System
510(k) Summary

Submitter: Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

Contact Person: Richard Treharne

Trade Name: PYRAMID™ ANTERIOR PLATE Fixation System

Classification Name: Spinal Intervertebral Body Fixation Orthosis, Class II

Predicate Device(s): The PYRAMID™ ANTERIOR PLATE Fixation System is substantially equivalent to K922543, Sofamor Danek ZPLATE-ATL™ Anterior Fixation System, which was cleared on May 19, 1993 and the BUTTERFLY™ PLATE Fixation System (K010632) which was cleared on May 31, 2001.

Device Description: The PYRAMID™ ANTERIOR PLATE Fixation System is a supplemental fixation construct consisting of a variety of shapes and sizes of plates, and screws, as well as ancillary products and instrument sets. The PYRAMID™ ANTERIOR PLATE Fixation System implant components can be locked into a variety of configurations, with each construct being tailor-made for the individual case. The implant components are made of titanium alloy (Ti-6A1-4V) described by ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used together in a construct.

Intended Use: The Medtronic Sofamor Danek PYRAMID™ ANTERIOR PLATE Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures.

When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5)Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele; and/or 11)

	Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.
Functionality & Safety Testing:	Mechanical testing was performed on the PYRAMID™ ANTERIOR PLATE Fixation System, which determined it to be substantially equivalent to the ZPLATE-ATL™ Anterior Fixation System and the BUTTERFLY™ PLATE Fixation System.
Conclusion:	The PYRAMID™ ANTERIOR PLATE Fixation System is substantially equivalent to K922543, Sofamor Danek ZPLATE-ATL™ Anterior Fixation System (SE 5/19/93) and to the Medtronic Sofamor Danek BONE GRAFT WASHER (K994122 SE 12/06/99).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K013665
Trade Name: PYRAMID™ Anterior Plate Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 4, 2001
Received: November 6, 2001

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013665

Device Name: PYRAMID™ ANTERIOR PLATE Fixation System

Indications for Use:

The Medtronic Sofamor Danek PYRAMID™ ANTERIOR PLATE Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures.

When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5)Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use X **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013665